

## September 9<sup>th</sup> CSPA meeting

**Who – Advisory group and other interested parties.**

**When - September 9<sup>th</sup>,2009 from 9:00 a.m. to 3:00 p.m. (PDT)**

**Where - ‘Seoul Room’ at Sea-Tac airport near Seattle, WA.**

### Participants

#### Advisory Group Members- highlighted names were present

Name	Representing
Mike Dwyer CAE Rick Locker (RL) by phone	Juvenile Products Manufacturers Association
Sheela Sathyanarayana MD MPH	Seattle Children's Hospital
Arthur Kazianis (AK) by phone Alternate - Kathrin Belliveau	Hasbro
William (Bill) Struyk (BS)	Johnson & Johnson
Thomas Head (TH) Alternate - Jennifer Sommer (JS) by phone	Wal-Mart
Elizabeth Davis (ED)	League of Women Voters
Bob Knight	Find It Games
Laurie Valeriano (LV)	WA Toxics Coalition
Karen Bowman MN, RN, COHN-S	Karen Bowman & Assoc. Inc.
Kathleen Shaver (KS)	Mattel
John Williams (JRW)	Washington State Department of Ecology
Denise LaFlamme (DLF)	Washington State Department of Health

Other people attending in person:

Bill Alkire (BA) representing TIA

Andy Hackman (AH) representing TIA

Mark Johnston (MJ) representing Washington Retail Association

Jim White (JWW) from DOH

Alex Stone (AS) from Ecy

Allyson Zipp (AZ) from AGO for Ecy

Carol Kraege (CK) from Ecy

Chris Teaf (CT) representing Mattel/TIA

Holly Davies (HD) from Ecy

Mark Greenberg (MG) representing ACC

Other people attending by phone:

Francis Wu (FW) representing the Personal Care Products Council

Kathleen (Kathy) Willy (KW) representing Johnson and Johnson

## Introduction

JRW opened the meeting and reiterated that the purpose is to get clarification on the respective positions submitted in written comments. This is not the forum to debate the issues. JRW read all the draft comments and gave out his list of questions in advance to the meeting participants.

JRW put in bold those who he directed the questions to, but everyone is welcome to comment on them.

JRW went over the process and timeline, which is also on the CSPA website<sup>1</sup>. The process was designed to be transparent, and save time and money. The process allows for comment by the advisory committee and public.

JRW explained the pilot rule. If there are no volunteers, then Ecy will not do a pilot rule and will go directly to final rule writing. Participants pick which parts of the pilot rule to test. Ecy does not expect reports to be submitted during the pilot phase. Ecy would like participants to look at costs, barriers, and issues, as if the pilot rule would be applied. John will write a report at the end of the pilot phase. There is no limit to the number of participants in the pilot rule.

There were questions on the timing of the pilot rule.

JRW explained the pilot is expected to start in January and last four months, but it is flexible.

ED asked about the availability of notes. JRW replied that the notes will be totally available and public. Everything is available on the website. Notes from meetings with individuals are also available to everyone.

## Issues

- 1) **Everyone** - What do you think 'a violation' means? For example if I manufacture 20,000 'children widgets', and it turns out they have 3 chemicals which are on the reporting list, but I failed to report them. Would this incident be 1 violation, 20,000 violations (each unit counts as a violation), or 60,000 violations (each unit times the number of unreported chemicals counts as a violation)?

ED-  $\$5000 \times 20,000 = \$100,000,000$ , which seems too much, but  $\$5000 \times 1$  seems too little.

KS- One violation of the reporting requirement should apply for the product line.

AK- If a violation is found, should the manufacturer have an opportunity to present his case to the state?

JRW- There is no formal application for relief like most laws, but we usually allow an opportunity for response and fact checking.

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<sup>1</sup> <http://www.ecy.wa.gov/programs/swfa/rules/ruleChildSafe.html>

AH- They are not reporting each unit, so it's one violation of the reporting requirement. We should deal with the number of chemicals on a case by case basis. We need due process. The public response is the true penalty. Ecy should work with manufacturers if we find a violation.  
CK-What does KS mean by "product line?"

KS- Distinguished SKU numbers from product lines. She gave an example of a fashion doll packaged differently for different retailers. She mentioned this is also a question for the reporting process.

TH- Need to capture information on front end to report on back end. Things that differ in size or count that have the same basic composition. One component may appear in several different products with different UPCs. They would trace back with UPC codes.

AH- Brought up a related issue because trade associations are allowed to report. What if TIA is reporting for different manufacturers and there is a violation? That may impact flow of information.

- 2) **WSRA, TIA, PCPC, JPMA** For the position: "there should be exemptions for chemicals on certain list e.g. GRAS" – do you mean if the chemical is on the GRAS list than the chemical should not be on the CSPA reporting list, or do you mean the reporting trigger amount should not be less than the 'de minimus value' set in such list? For example – the chemical FORMALDEHYDE is on GRAS, so are you saying that FORMALDEHYDE should be considered 'safe' and therefore not be on the reporting list – or are you saying that the reporting trigger amount should not be less than the 'de minimus' value established in the GRAS list?

AH- GRAS is a use-based list by FDA for food. Those uses and intended applications should be exempt from our list.

ED- She has concerns about GRAS list. There are chemicals on GRAS list that should not be on the list and some have been removed. She has a concern about use of general purpose list for our specific purpose.

JRW- Clarified that food is not covered by our law (CSPA).

AH- Gave an example of a pesticide approved by EPA that might be used.

Someone on phone (?) - There is a sub list within GRAS for chemicals that contact food, so some might apply to CSPA.

CT- The greatest utility of GRAS may be the acceptable numbers assigned for individual chemicals. Could use that number as threshold.

RL- Part of the process is to survey landscape for exposure limits and safe harbors. Some chemicals are present in amounts that don't present a hazard. This is a crucial step in toxicology. He gave an example of formaldehyde. There is the overall regulatory structure and thousands of local laws.

TH- Chemical measurements vary by how you measure in different product categories- furniture, textiles, lotions, etc. We need to take into account intended use, ages, and exposures.

- 3) **WSRA, TIA, PCPC, JPMA** – you took the position, 'the reporting list should be limited to those chemicals used in the manufacture of the products' – are you willing to provide us with a list of these chemicals?

JRW gave an example of industry lists of chemicals to avoid, like the textile industry. It would be helpful if you could tell us what chemicals are in product categories that should be on the list. Some people have already suggested metals used in dyes for the list.

RL- Stated this approach is backwards. The intent of the law is to identify chemicals that are of concern and what should not be used in children's products. Then it becomes helpful for industry to tell Ecy what categories the chemicals are used in. Wants scientifically sound list with exposure limits first.

JRW- California cosmetic list has many items that are not in cosmetics. Our process takes into account potential exposure from children's products.

CT- Does it matter if there are things on the final chemicals list that aren't in products?

Presumably the selection process is taking that into account.

Someone replied that they would take up space on the list.

- 4) **WTC** – you took the position ‘it is reasonable to include contaminants in the reporting list as their introduction into the product can be avoided’ Do you think this is true for ‘all’ chemicals or just those which are clearly the result of poor manufacturing practices?

LV- Where there is evidence, like for nonyl phenol, that chemicals are ending up in products, then it should be reported. Disclosure is important.

JRW- Clarified pervasive chemicals compared to ones introduced.

LV- Manufacturing process or certain feedstock being used.

CT- Explained that nonyl phenol is a component of some detergents that is broadly applied. It is not used in formal manufacturing process, but may be being used in the facility. Another example is releasing agents in molds (silicone based products) that may be present. There needs to be a determination of importance of “presence vs significance” in making short list.

LV- Are they more likely to be in certain products and not as a contaminant?

JRW- Getting the concentrations for industrial use from industry would be helpful.

RL- Generally in the manufacture of solid products, we don't find high levels of contaminants that are potential HPCs. As long as we don't measure chemicals at any level, but focus on exposure, the issue resolves itself.

KW- Echo what last speaker said. Her concern is that you can detect every chemical, and we need to draw a line.

- 5) **WTC, Sheela, Elizabeth** - For the position: “the amount which should trigger reporting should be the detection limit – in other words there should be no ‘de minimis’ value” – what do you mean by ‘detection limit’? – I used to manage a certified lab, one of the things I learned is that the ‘detection limit’ varies by a number of factors including: the analytical method, the matrix the chemical is in, how much money you can spend, and lastly the currently available technology. Consequently ‘detection limits’ are never truly static, and can reflect the state of technology more than other considerations.

LV- Risk based levels also change, but at a slower pace than detection limits. Ecy needs to figure out reasonable methods that are appropriate for the few labs that do this sort of testing. Ecy should provide guidance for recommended analytical technique. This law is not about setting safe standards for chemicals. It's about identifying chemicals and finding out where they are.

How could we even choose risk levels? Consumers should have decision making power after getting information.

ED- If a chemical can be detected in a children's product, it should be reported. There is a certain level that can't be detected. It has to be looked at. Whatever is the accepted method for detecting should be used.

AH- Concern that it becomes too broad with no detection limit.

AK- Using the detection limit contradicts the principle of risk assessment.

JRW reminded everyone that today is not about debating, but about clarifying. Andy and Arthur's positions were clear from their write ups.

RL- It's even grayer. He gave the example of recent experience at the federal level with phthalates. An analysis of the problems they are encountering is informative for us. There is an enormous practical problem. They found the cost of testing and the burden to test materials that don't contain the substance, is untenable. There are consequences to small businesses and inexpensive products. The process of having a limit to test to and choosing which products need to be tested is important.

CT- Usually people have something in mind (e.g., a particular analytical method) when they say detection limit, and there are many methods. Specifics need to go into rule or guidance or something.

- 6) **TIA and JPMA** For the position: "Selection or prioritization of the substances for inclusion can be accomplished by joint review of specific existing lists and input from industry on relevant manufacturing materials. It is likely that all of the 50 available "slots" on such a 'reporting list' will be filled quickly by general agreement." What are the 'specific existing lists' you think are appropriate? Are you willing to go ahead and provide your proposed reporting list?

JRW further explained that he read draft comments about doing a full blown quantitative risk assessment and to just look at existing lists.

AH- Lists can be informative in process, but should not be the sole basis for the listing of a chemical. We need to look at the purpose and goal of each list. The lists should not be the ultimate decider and Ecy should not just count up how many lists a chemical appears on. There is a risk based element- exposure and exposure of concern.

JRW- Our report has some of the lists we have looked at. We would like people to look through the report and tell us which lists would be of particular value.

AH- We can be informative on that point.

- 7) **TIA and JPMA** seem to be sending a conflicting message regarding the need for a quantitative risk assessment for the reporting list. In the issue statement both parties express the position in #6 above, while in other documents received by these same two parties there seems to be a great deal of emphasis on quantitative risk assessments. So please be ready to clarify what your message is for this topic, on the 9<sup>th</sup>.

JRW said this was covered with discussion on #6.

- 8) **WSRA** – for the position 'It is critical that information collection be based on intended formulation. Accidental contaminants must be addressed on the back end in the

surveillance monitoring component.’ Are you saying that you want to rely on formulation and auditing/certification to control what is in your products, but if ‘off the shelf’ sampling should find contaminants they should be reported?

TH- Usually we see it at a component level. For example, if we switch suppliers quickly for a component and there was no established vetting, we may pick up a contaminant. We need a process to identify on the backend. He gave an example of the Toxics in Packaging Clearinghouse (TPCH) report results and contaminant levels were informative. The results were counter to our assumptions. Issues were not where they were expected, so it is important to test on the backend. Unexpected chemicals occur in “crisis” situations where you need a new supplier right away. There should be a combination of surveillance (QA in trade associations and state working in harmony). TPCH again is a good example of working well.

- 9) **WSRA** – Can you provide what the specific ‘data sets’ are that you reference in your comments?

JRW further explained that there is a movement in the manufacturing world to trace chemicals in products. The WSRA draft comments suggested that states should use similar data sets.

TH- To the extent they’ve been developed. Wal-Mart is working on two fronts. GC3 with Lowell workgroup to create minimal chemical data set (they expect to present findings at a meeting in Spring 2010). GS1 workgroup focused on how do we capture chemical components. They are developing standards and are on track for the proposal to be vetted in the third quarter of 2009. All looking long term at green chemistry and chemical component reporting and how to capture the information along the chain.

JRW- Mentioned Ecy’s work with Lowell Center and IC2.

AS- Added that Ecy is a member of GC3.

Link to GS1 standards paper -

[http://www.gs1.org/docs/gdsn/GDSN\\_Business\\_Bulletin\\_Chemical\\_Ingredients\\_20Mar09.pdf](http://www.gs1.org/docs/gdsn/GDSN_Business_Bulletin_Chemical_Ingredients_20Mar09.pdf)

- 10) **WSRA** – for 1k, you state, ‘In light of this, there should be some high priority chemicals that should be restricted from being intentionally added.’ Does this mean for some chemicals ‘any’ amount is too much, so if ‘any’ amount is found it must be reported?

JRW- Reiterated that the current law does not give authority to ban anything.

TH- You may find some, depending on product category and application. For example, food contact surfaces may have more stringent limits than furniture. This is a concern for prioritization.

- 11) **WSRA** – referred to ‘product categories’ in your write-up, please be ready to provide a list of the categories you are envisioning for the meeting on the 9<sup>th</sup>

JRW- It would be helpful to get categories from everyone in industry to help craft rule language.

TH- We would go back to GS1 and the global product classification codes. This is a hierarchy that is useful at multiple levels. We should use definitions that are already industry standard. Tom will send link to the group.

AH- Along the same lines as TH. The product category should be more defined than “Barbie dolls.” It shouldn’t be a brand name.

LV- How is that useful for consumers? They need more information.

AH- Clarified that the use of generic product categories is not for reporting, but for testing methods and exposure/de minimis limits of concern.

JRW- Brought up also for phasing in of reporting.

ED- Goes back to #8 and back end surveillance. Who is going to do it?

JRW- Probably, if a company says chemical is not in place because of knowledge of manufacture and supply chain, then we would require some back end testing and other components.

ED- Will there be monitoring by Ecology?

JRW- Our resources won’t allow us to buy and test many products

AH- Question on reporting category. Would we want a statement that it’s not there?

JRW- No, you only have to report presence. He hopes nobody has to report anything because the chemicals are not there.

AK- He has a concern related to technology and what is technologically feasible. The rest of the world recognizes that electronic components contain HPCs with limits. Ecy needs to recognize that or else run the risk of banning products.

Link to GS1 global product classification codes–

<http://gpcbrowser.gs1.org/>

- 12) **Sheela** - Please be ready to clarify the statement ‘Where there is no literature the scheme should be protective.’

Sheela was not present to clarify her statement.

- 13) **JPMA** - please clarify what you mean by “efforts should be undertaken to avoid non-tariff based trade barriers.” And how you think the CSPA could create such barriers?

RL- There are laws coming into effect with lesson on risk and practicality. Lesson exacerbated by Consumer Product Safety Improvement Act of 2008 (CPSIA). There are problems when you do not have consistency in developing standards. There are complaints to trade reps and embassies that some of the US provisions based on restricting limits in a product without further clarification have become non-tariff trade barriers. There is a huge discussion on heavy metals and performance standards for cribs. There is an increasing global sensitivity on this.

JRW- This is a reporting law, but manufacturers are seeing this as an effective ban.

RL- Irony is that we used to make the complaint about other countries. This is new to the political landscape.

- 14) **JPMA** – your position seems to be ‘that the manufacturers of the raw material, i.e. chemicals; not the manufacturer or the final product, should be the responsible party for reporting.’ How do you think the current definition of manufacturer in the CSPA would provide Ecology the authority to do this?

RL- More about how to efficiently get information we want to get. We want to avoid duplicative or burdensome reporting requirements for downstream users. We should look at Green Chemistry and other efforts to compile information. This invites the question about whether there is a more efficient way to get information without putting too big a burden on local Washington State businesses. Local reporting requirements run risk of disparate burden. The law doesn't exclude other ways of getting information. Statutory language defines manufacturers, but does not exclude other groups. We could get information from more upstream groups like resin makers. Manufacturers may not have direct knowledge needed for reporting and we should accept upstream information (MSDS, resin makers, materials suppliers).

AK- The process Rick is describing is being used extensively in Europe. It depends on the original manufacturer who has all the toxicological and risk assessments.

JRW- Trade associations could identify suppliers for different categories and disperse information to members.

AH- There are issues with confidential business information, not influencing supply relationships, and anti-trust. Supply relationships are sometimes very guarded.

RL- You are not locked in and have alternatives. The goal is to collect information, but in an efficient manner that is not burdensome.

CK- The law includes the definition of manufacturer as someone who "produces a children's product," which makes it hard for us to require a report from a resin manufacturer.

RL- Trade associations may be helpful. To the extent we can identify common materials, we'd like Ecy to say it's acceptable reporting.

TH- Wal-Mart has been looking at the fragrance industry as a model. There is risk and hazard information upstream that is pushed through the whole system. John asked for a name and Tom said definitely.

Links to Fragrance Industry Efforts -

<http://www.ifraorg.org/Home/Code,+Standards+Compliance/IFRA+Standards/page.aspx/56>

<http://www.rifm.org/about.asp>

JRW- Part of an acceptable self certification might include this.

RL- During the review of CPSIA requirement for certification there was the realization that you could have passive systems or on demand systems for collecting information.

JRW- What about a centralized reporting system/clearinghouse? It's not in the law and we do not currently have money for this. How do people react to that as an optional system with fee?

RL- Don't lock yourself into one approach with changing technology. One-size approach will not work for everyone.

LV- Wants more specific example of how resin manufacturer would work.

RL- It depends on the chemicals and risk, and what has to be reported. Is accessibility a qualifier? Let's assume an inaccessible electronic component not meant to be reported. A plastic shell may be used for several products (toy, car seat, cosmetic case, etc.). Not likely to be subject to contamination. The manufacturer would buy resin and mold into whatever needed. Get information from source, which is the resin formulator (who sells the pellets). This is an efficient way to get information on that component.

LV- Dow [Dow was used an example of the resin manufacturer] would report what to Ecology? They are making resin with BPA that can be used for certain products?

RL- We don't have a mechanism yet.

AK- He used a BPA example. Certain epoxies use BPA (like on electronics). This is an accepted practice since it's not accessible. However, if we say BPA can't be used in baby products.

Laurie- Law is reporting not ban.

RL- The resin maker can give information. Should there be restrictions on BPA? Polycarbonate lenses are useful and about safety.

JRW- Dow saying this might be used does not satisfy the reporting requirement in the law. John see the use as moving information from resin maker to manufacturer to Ecology.

RL- The resin maker could produce a matrix of plastics and what is in each.

LV- How does this remove the burden?

RL- In the real world market place with lead and phthalate restrictions, we've discovered if you allow a test based solution, it's costly and inefficient. There are benefits to moving this upstream. Obviously someone has to tie it together. Ecy should recognize information from different sources.

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### **Topics others on the advisory group would like clarification for:**

For those of you who said 'no de minimus levels are acceptable' - If a "de minimus" level is set as a no effect level, based on sound risk assessment methods, would that address your concerns?

RL- Referred to statutory language for the definition of a HPC. In defining chemicals to be selected and identifying HPCs, chemicals identified on the basis of "credible scientific evidence." There is a definitional context and it is an important qualifier of the legislature that HPCs are based on credible scientific evidence. Ecy needs to do an assessment that includes exposure, and accept that there is a level that has no effect.

JRW- The process takes that into account and they will see process and chemical examples later in the fall.

Ten minute break.

John's goal has been met and he opened the floor.

### **Additional Concerns**

JRW- At the end of the discussion there was this idea of moving upstream for information, but there are two interpretations of what was said. John also encourages people to make it clearer in their final comments.

- a. TIA and JPMA suggest that the resin manufacturer could report to Ecology
- b. Part of a self certification program could include information provided by the resin maker to the children's product manufacturer.

AH- Details about products are needed to fulfill the statute. Dow [still being used as the example of the resin maker] could provide information to Ecy and then the manufacturer references that

resin used in a certain application. Another option is that TIA could state this resin has been used and this is what is in it. It depends on how the supplier relationship works out. We can test in rule which is more efficient.

LV- Information from resin manufacturers would be helpful before the rule.

AH- It could provide an audit function afterwards.

AH- The resin maker might not want to provide information to manufacturer to keep formula secret.

MG- He agreed with Laurie that we don't have a legal hook to go after chemical manufacturers.

AH- Upstream manufacturers report in REACH, and then the downstream manufacturers reference it.

ED- What is a sound risk assessment?

CT- A sound risk assessment does not need to be quantitative, but has to take into account toxicity and exposure. The UW/DOH process needs to be, and presumably will be a form of sound risk assessment. It depends on the product, chemical, and amount of information available. The data for first 50 on the list are probably better than that which will be available after the next few hundred.

ED- What time period are you looking at for risk assessment?

CT- Could be several time periods- acute, chronic, repeated for years, etc. A risk assessment lays out assumptions for other people to critique. A sound risk assessment is judged by reviewers. You want someone else to read it and say it's good.

LV- Are you suggesting each product category needs a risk assessment for each chemical?

CT- I am not, but John brought it up, so someone must have suggested that.

JRW- There were comments on quantitative risk assessment and existing lists.

LV- Gave the example of risk assessment for flame retardants in sleepwear.

CT- We need something like a risk assessment to know if inclusion on the list or a proposed threshold level is reasonable.

LV- Our position is that presence is enough. Cost effectiveness of implementation is the agency's issue.

CT- We can't separate information from how that information is used; there must be a way to distinguish between presence and safety or significance. We need to know if it means something that it's present in the product.

JRW- The process takes into account hazard and exposure and whether there is an analytic method, politics, and other considerations. John sees product categories coming into play for phases of reporting.

More about supplier information when Rick returned.

RL- Agrees that a report from Dow wouldn't suffice under the law. He can see both scenarios happening. Manufacturers should not have to test for chemicals that are not in certain materials.

AZ- What if chemical X is in the resin and Dow said it wasn't? Does the liability go to Dow?

RL- In liability law, you wouldn't face liability if you acted reasonably and prudently, like relying on Dow's report.

FW- She is confused on the notion of supplier reporting. When would they be asked to report and by whom? There is the issue of trade secrets and supplier relationships. In the California cosmetics act, the manufacturer identifies a supplier to CA to pull supplier in.

JRW- I'm comfortable with a manufacturer using information from suppliers, but the manufacturer needs to make sure the suppliers' information is correct. The goal of the law is for manufacturers to know what is in their products.

AH- This goes back to due process and dealing with each violation on a case by case basis.

TH- He illustrated the scope of what we're trying to ascertain with vending machine products. Reporting requirements need to go upstream and use trade industries to figure out mechanics of how it will work in their industry.

JRW- Agrees on the importance of trade industries in the process.

TH- There are issues in how information gets passed along.

AS- Ecology has seen these issues in our Toxics in Packaging law. Ecy recommends to manufacturers that they get information from suppliers and occasionally test. This is working fairly well.

TH- He is worried about keeping products on the shelf, not the fines. TPCCH is a good example.

RL- This shows importance of what chemicals should be included on the list and what levels trigger reporting. There are still questions on what is or is not packaging.

TH- Industry did not effectively create an infrastructure for compliance with TPCCH.

AH- There is an issue of reporting for a chemical that is accessible in one product and not accessible in another. Will there be different reporting requirements?

JRW- That has not been decided. The purpose of the law is to let the consumer know. You are allowed to include other information in the report.

CT- He wanted to bring up that the form of a chemical is important and he would like clarification on how exactly chemicals would be listed for reporting, such as "vinyl chloride" and "styrene". They are a problem in monomeric form at certain levels. However, the products use polymers, so there are only residual monomers. Depending on manufacturing process, there may be no residual monomers. Will the list say monomeric styrene or styrene?

AS- No final decision has been made. He have a recent example from Ecy's Hazardous Waste Program. Ecy exempted polymeric species, but put restrictions on the average molecule weight to limit monomers. Ecy hasn't looked at it in too much detail, since we don't know if styrene or vinyl chloride will be on list.

RL- There is a fundamental issue of presence in the end product at amounts that are risky.

CT- Dr. Stone's clarification was reasonable. I can see several different ways to handle this and I will add more to my comments.

JRW- The process will be open to comments and changes.

LV- Is the decision to not include lead, cadmium and phthalates on the list related to preemption?

JRW- Yes.

LV- What happens if the federal assessment on phthalates reverses the ban?

JRW- Then those phthalates would no longer be pre-empted.

LV- I thought the legal opinion last year was that the disclosure piece in our state law was not pre-empted because they are not standards.

AZ- I will not go into my legal advice to Ecology.

JRW- There are a limited number of slots and we don't want to use any on chemicals that are being regulated in other ways. We'd like to focus on other chemicals of concern that are not being addressed. It's not worth extra hassle for potential gain.

Meeting ended early – about 1:00.